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**Testimony Before the Special Committee on Aging
United States Senate
The Honorable Gordon Smith, Chair
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Internet Pharmacies and Prescription Drug Importation

Thank you for the opportunity to appear before this committee for the discussion of Internet pharmacies and prescription drug importation. I am delighted and honored to be here on behalf of the Oregon Board of Pharmacy to describe the Board's recent experience with regard to the distribution of drugs via the Internet and the importation of prescription drugs from foreign sources. As described in my curriculum vitae and introductory bio which was provided to your committee staff, I am currently serving as a member of the Executive Committee of the National Association of Boards of Pharmacy (NABP). My appearance here today is in no way connected with or related to my position or responsibilities with the NABP. I am appearing solely on behalf of the Oregon Board of Pharmacy in my capacity as the Board's executive director.

The Oregon Board of Pharmacy was established in 1891 by the Oregon Legislature to administer the first Oregon Pharmacy Practice Act, and has met regularly for this purpose since its inception. The Board, the profession of pharmacy and the manner in which health professions are regulated have evolved significantly in the past 100 years.

Today, the Board of Pharmacy is the sole Oregon agency whose mission and responsibility is to regulate the practice of pharmacy and the quality and distribution of drugs in the state in the interest of the public health, safety and welfare. In this respect, the Board of Pharmacy differs from the other health professional regulatory agencies such as nursing, dentistry and medicine. Not only does the Board of Pharmacy regulate the professional practice of the individual licensees, pharmacists, pharmacy technicians and pharmacy interns, but it also must regulate the various drug outlets involved in the manufacture, storage and distribution of drugs and controlled substances in the state. It is in the context of this responsibility for the quality and distribution of drugs that the Board of Pharmacy has become involved in the drug importation question.

The Board of Pharmacy agrees that patients need and deserve access to necessary safe, effective and affordable medications. It also understands that the method of pricing of pharmaceuticals in the U.S. differs from methods used in many other countries. The U.S. depends upon market forces to set prices while many other governments regulate drug prices. This is, in a nutshell, the reason some drugs are less expensive in Canada and other countries, and why so much interest has been generated around foreign drug importation.

For the past four years the Oregon Board of Pharmacy has been engaged in discussions with its members and staff, and with a variety of external stake holders regarding the cross border sale of prescription drugs. The Oregon Board has also been involved in ongoing research into the legal and safety issues related to the distribution of drugs across foreign borders, in particular, the Canadian border. Initially, the issues revolved around U.S. citizens crossing into Canada to have prescriptions filled at Canadian pharmacies, and around the apparent increase in prescription drug sales over the Internet. The Board's belief was that these activities were in violation of federal law and probably of state law as well. It took the position to monitor the activity rather than initiate any enforcement action, and continue its discussions with and take its lead from the National Association of Boards of Pharmacy (NABP), the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA).

In the summer of 2001 the Board was made aware of a store front business operation in Eugene acting as a "prescription broker", soliciting patients to bring their prescriptions in to have them sent to Canada to be filled. These "brokers" would arrange to have the prescriptions filled in Canada by Canadian pharmacies and mailed directly to residents in Oregon. These businesses were proliferating across the country and appearing in virtually every state. The Board became aware of fifteen such outlets in the state through reports from pharmacists and consumers. It has been estimated the number may actually have been as high as thirty.

Soon, the Board of Pharmacy began to receive complaints from pharmacists, as well as from consumers, about these little understood self proclaimed "middle men". The Board became alarmed at the sudden proliferation of this unregulated distribution of prescription drugs into the state. In March of 2002, the Board issued a press release to alert consumers to the legal and safety concerns. In February of 2003, an article describing the Board's position was published in the Board of Pharmacy quarterly newsletter and placed on the Board's website.

Around the time the Board began to investigate these prescription brokering establishments to determine if they were operating in violation of state law, the FDA, the NABP, state boards of pharmacy and courts across the country were presenting clear policy statements on the legality and safety risks related to such operations. The FDA, state boards of pharmacy and courts began to take action against these entities for violations of state and federal laws.

In October of 2003, the Oregon Board of Pharmacy issued warning letters to a number of prescription brokers identifying the possible violations in which they could be engaged and the potential actions the Board could take for continued violation. As part of its ongoing investigation, the Board issued subpoenas to several of these outlets in an effort to gather information about their business practices. So far, all but one has, on advice of legal counsel, opted to cease operation in exchange for the Board's promise to drop its investigation, rather than respond to the subpoena and let the Board clearly evaluate its operation. The Board is aware of one remaining prescription broker that has not agreed to close. In this case, the Board has proposed disciplinary action in the form of a civil penalty against the business owner pursuant to the Oregon Pharmacy Act. The case is still pending.

The Board has been made aware through various anecdotal reports that a number of Oregon citizens are continuing to purchase prescription drugs through drug distribution sites on the Internet. Some of these Internet sites are legitimate pharmacy operations that remain in full compliance with the laws regulating the practice of pharmacy and the distribution of drugs. Some provide prescription medications without demanding a prescription as required by law. Some are not even pharmacies, but are fraudulent rogue sites pretending to be pharmacies. This has been a cause of concern for the Board because these sites are very difficult to investigate. The legitimate sites make identifying information readily available on the home page. The rogue sites avoid detection by failing to identify names of the doctors or pharmacists and disguising their location while continuing to display an appearance of legitimacy. The Board's compliance staff has been unable to keep up with its normal inspection and investigation work load. There is simply nobody available to investigate these Internet sites beyond a few very cursory initial steps. However, if a complaint is filed against a foreign pharmacy or Internet web site, a full investigation is initiated. The Board's compliance program is complaint driven.

Several suspect Internet web sites have been brought to the Board's attention, but none of these has been thoroughly investigated. Only one complaint has been filed with the Board against a Canadian pharmacy for providing an Oregon patient with the wrong drug. This was a case in which a Portland woman requiring treatment for breast cancer had her prescription filled by a pharmacy in British Columbia. The pharmacy erroneously filled her cancer drug prescription (tamoxifen) with a ninety day supply of a drug to treat high blood pressure (lisinopril). This not only caused a three month delay in her cancer treatment, but the woman suffered a significant adverse reaction, not uncommon to that particular class of drug, that required further medical treatment and follow-up. The impact on the outcome of her breast cancer as a result of this delay and adverse drug reaction may never be known. The Board of Pharmacy attempted to investigate the complaint, but was unable to locate the pharmacist or establish cooperation with the pharmacy. The case was ultimately referred to the investigative agency in BC, the College of Pharmacists of British Columbia. After several months and several attempts to contact the investigator, the Oregon Board eventually received notice that no action would be taken against the pharmacist or the pharmacy.

The Oregon Board of Pharmacy does not believe the long term solution to the complex prescription drug pricing issue lies in Canada or any other foreign country with government price controls. The solution lies in meaningful health care reform legislation that can address existing legal and safety concerns in our own country, and provide affordable access to prescription drugs for citizens at home. Our citizens should not be subjected to the unnecessary risk of unregulated access to medications of unknown quality from foreign countries. Federal and state laws exist to ensure the dispensing of safe and effective medications to U.S. patients. Allowing and encouraging the importation of medications from other countries without the appropriate regulatory safeguards is a serious threat to our established and traditional regulatory foundation and to the health and safety of our most vulnerable population.

The topic of prescription drug distribution via the Internet is broad and complex. To effectively analyze the related public policy issues that exist, this broad context must be

dissected into its major components. Those who sell drugs over the Internet fall into one of three categories. They are either pharmacists dispensing drugs through a legitimate licensed pharmacy regulated by the state boards of pharmacy, they are legitimate licensed prescribing practitioners regulated by their state professional regulatory agencies (board of medical examiners, board of dentistry, etc.), or they are neither authorized dispensers nor authorized prescribers. Individuals in these categories are operating fraudulent rogue web sites deceiving consumers into believing they have some authority to prescribe, dispense or distribute prescription drugs. These are the sites advertising prescription drugs without a prescription. These are the criminal elements that evade the resources and authority of the states and they exist both inside and outside the U.S. This is where the resources and authority of the federal government and Congress is sorely needed. The state boards of pharmacy and medicine can handle pharmacists and pharmacies and doctors in the U.S. However, the states are helpless in the face of the invisibility, anonymity and covert mobility of rogue sites on the Internet.

The following list describes the concerns that the Board believes must be addressed by any federal legislation being considered.

1. Canadian pharmacists are prohibited by Canadian law from filling prescriptions written by U.S. physicians. To circumvent this law, Canadian pharmacists employ Canadian physicians to re-write prescriptions on their Canadian prescription forms, which means the prescription written by the U.S. physician is never filled. It may be simply filed away and stored in Canada, or it may be destroyed by the local prescription broker in an effort to "cover their tracks" while a facsimile of the original prescription is transmitted to Canada. In either case, the Canadian physician takes no responsibility for the therapy or therapeutic outcome for the U.S. patient, and there is a risk that the original prescription written in the U.S. may have been written by someone who is not a licensed practitioner authorized to prescribe. Any plan that allows importation through Canadian pharmacists will continue to encourage and promote this "slight of hand" manipulation of the prescription, which violates legal, professional and ethical standards of both the U.S. and Canada. And, under current laws, the state Boards of Pharmacy cannot intervene if an error, injury, adverse outcome or death occurs when the drugs have been imported from another country.
2. The Board believes that the problem is not that drugs in Canada are "bad" or "inferior". Canadian people are healthy and are not falling dead because their drugs are bad. The Board's concern is related to the mechanisms and processes of retail drug distribution by Canadian pharmacies. If we allow importation of drugs from Canada, we must guarantee that the drugs received by U.S. citizens are the same as the drugs received by Canadian citizens. Unfortunately, ample evidence now exists to show that many drugs are passing through Canadian pharmacies from other countries, unregulated by Canadian or U.S. authorities, to unsuspecting U.S. citizens. The unregulated distribution of drugs into the U.S. creates a health risk to citizens by creating opportunities for the unscrupulous introduction of outdated, contaminated, or counterfeit drugs. It also creates an avenue for the introduction of drugs that have been illegally or improperly manufactured in another country. These tainted prescription medications could be easily dispensed

- by unregulated rogue web sites or by "passing through" pharmacies in other countries such as Canada, Germany or Great Britain from their unidentified country of origin. Closed distribution channels that eliminate the risk of and the opportunities for the unscrupulous introduction of counterfeit or inferior drug products must be established and enforced. No matter where the safe and effective drugs originate, the state Boards of Pharmacy must ensure that a distribution system remains in place to guarantee that the drug product prescribed for and requested by the patient is exactly what the patient receives.
3. If importation of drugs from Canada is to be allowed under some type of regulated mechanism, it should be between the Canadian pharmaceutical wholesaler and the state licensed pharmacy in the U.S. This eliminates the prescription "slight of hand" manipulation by the Canadian pharmacist and physician that will lead to errors, and it puts the U.S. consumer back in touch with their own local pharmacist. It may be possible for drugs to be imported from a known safe foreign source through closed regulated wholesale distribution channels. Involvement with a very small number of Canadian wholesalers would provide a much more manageable safety risk and regulatory work load than a relatively large number of Canadian pharmacies and pharmacists. Additionally, The Board believes it is very important that even if a safe source of drugs from another country is available, the professional practice of pharmacists for U.S. citizens must remain subject to regulation by the U.S. states in which the pharmacists are licensed. The professional practice of pharmacists cannot be imported from a foreign country
 4. If drug importation at the wholesale level is to be allowed, the foreign wholesale drug outlet must be willing to be licensed by the state or states into which it is sending drugs and to have documented business relationships with any pharmacy in the states with which it does business. In addition, it must be willing to submit to the regulatory jurisdiction of the state as a condition of licensure. The U.S. pharmacies and pharmacists are already licensed under their state's jurisdiction.
 5. The Board of Pharmacy understands the hardships placed on many Oregonians and citizens across the country because of high drug prices. The Board also understands the risks associated with unregulated drug importation. The Board is working with the National Association of Boards of Pharmacy, the Canadian National Association of Pharmacy Regulatory Authorities, the FDA, Health Canada, the Oregon State Pharmacists Association, consumer groups, the Oregon Attorney General's office and Governor Kulongoski, studying ways to effectively address safety concerns and providing information to health professionals, legislators and consumers. The Board is also interested in working with state and federal legislators to identify real and lasting solutions to address Oregon and U.S. citizens' access to safe, affordable and effective health care.
 6. Oregon Governor Ted Kulongoski has proposed a pilot project that is currently awaiting approval from the Secretary of Health and Human Services. The "Pioneer Prescription Drug Project" announced by Governor Kulongoski in August of 2004 will allow prescription drug importation by Oregon pharmacists from Canada in a

controlled manner, regulated and monitored by the Oregon Board of Pharmacy. It is designed to improve Oregonian citizens' access to safe and affordable prescription drugs through Oregon pharmacies by providing appropriate regulatory guidance to pharmacists and pharmaceutical wholesalers. A description of the provisions of Governor Kulongoski's plan are included as an addendum to this testimony.

7. Even though the Internet provides vast opportunities for convenient access to a variety of legitimate products and services that may improve the quality of life of consumers, the Board is very concerned about drugs purchased through the Internet. Unsuspecting U.S. citizens are currently putting themselves at risk by purchasing prescription drugs via Internet sites which may appear to be legitimate pharmacies, but, in fact, may actually be unregulated rogue web sites without a licensed physician, pharmacy or pharmacist and may not be located in the U.S. If the U.S. Congress considers regulating pharmacy dispensing via the Internet, the Board urges that the Verified Internet Pharmacy Practice Site (VIPPS) model as currently administered by the National Association of Boards of Pharmacy (NABP) be adopted as the basis for regulation. The criteria for VIPPS certification provide assurances that the entity involved in dispensing is doing so in compliance with all applicable laws and regulations. In this way, the safety of U.S. consumers can be protected and the compliance with prescription dispensing regulations can be appropriately monitored.

The Board believes that the intrastate and interstate licensing and regulation of pharmacy practice and drug distribution legitimately belongs at the state level as it currently exists. The state Boards of Pharmacy, through their association with the NABP, have developed cooperative relationships with regard to professional licensing and investigations. However, the international distribution of drugs via the Internet far exceeds the resources available to the state agencies and the authority of states to enforce regulatory compliance by entities outside the country.

The Oregon Board of Pharmacy is the sole agency entrusted by the Oregon legislature with the responsibility and authority to regulate the practice of pharmacy and the quality and distribution of drugs in the state in the interest of the public health, safety and welfare. Because of the risks associated with acquiring drugs from foreign countries or via the Internet, consumers are urged to talk with their pharmacist or physician to ensure the medications they are receiving are safe, effective, affordable and appropriate for their medical condition. Often, less expensive alternatives are available through their doctor and local pharmacy.

On behalf of the Oregon Board of Pharmacy, I appreciate the opportunity to address the Committee and I thank you for considering these concerns as they relate to foreign drug importation and Internet drug distribution legislation.